

# **EXHIBIT 41**

# PAIN

## Opioid Therapy

### SHORT- VS LONG-ACTING OPIOIDS: WHAT'S THE DIFFERENCE?

#### Short-acting opioids

- ▶ Work more quickly
- ▶ Treat pain for a short period
- ▶ Taken as needed when you first start to feel pain

#### Long-acting opioids

- ▶ Are released in the body over a longer period of time so pain relief lasts for several hours
- ▶ Treat persistent pain
- ▶ Taken on a regular schedule (every 8–12 hours) at the same time every day

### EXPLAIN YOUR PAIN

**ONLY YOU KNOW HOW MUCH PAIN YOU ARE IN.**

**Be sure to tell your healthcare provider the following information about your pain to help him best treat it:**

- ✓ When it starts
- ✓ Where it occurs
- ✓ How long it lasts
- ✓ Any "triggers" that cause you pain

**Remember, having pain is *not* a way of life—all types of pain can be treated, and be controlled or decreased as the result of treatment.**



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*Opioids can be taken safely for pain relief. This handout will review some of the risks and benefits of opioid therapy, and what you can expect once you start taking an opioid medication.*

*Opioids* are used to treat moderate-to-severe pain (pain that is greater than 4 on a pain scale where 0 is no pain and 10 is the worst possible pain). They work like natural substances found in the body (known as *endorphins*) that are produced to control pain. *Hydrocodone* (Vicodin), *morphine* (Avinza, Kadian, MS Contin, Oramorph), *codeine* (Tylenol with Codeine, Empirin with Codeine), *oxycodone* (OxyContin, Percocet), *methadone* (Dolophine, Methadose), *fentanyl* (Actiq, Fentora, Duragesic), and *oxymorphone* (Opana) are the names of commonly prescribed opioids.

Opioids are either *short-* or *long-acting* (see "Short- vs Long-Acting Opioids" box), and can be used to treat *chronic* and *acute* pain. *Chronic* (or *persistent*) pain is present over a long period of time. Some examples include pain that is associated with a long-term illness or condition, such as arthritis, low back pain, or cancer. *Acute* pain is short-term and may be severe, for example, pain that is caused by an injury.

It is important to talk with your healthcare provider about the type of pain that you are experiencing. See the checklist on the left (*Explain Your Pain*) for some tips about communicating your pain level to your healthcare provider.

#### What are some of the benefits of opioid therapy?

Opioids can be very beneficial for treatment of both acute and chronic pain. Opioid therapy can:

- ▶ Reduce pain
- ▶ Improve pain-related dysfunction (that is, when your pain stops you from doing your normal activities of daily living)
- ▶ Improve quality of life

**As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:**

- ▶ Constipation
- ▶ Drowsiness
- ▶ Confusion
- ▶ Nausea
- ▶ Itching
- ▶ Dizziness
- ▶ Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

**Your healthcare provider will work with you to ensure that you are taking your opioids safely. As with all prescription medications, some risks are associated with opioid therapy. These include tolerance, physical dependence, withdrawal, and addiction.**

When patients become *tolerant* to a medication, it means that they need increasing amounts of the medication to give the same effect that occurred when they first started taking it. Once you are on the right dose of medication for your pain, tolerance usually does not occur. Unless your pain worsens, you will most likely remain on the same opioid dose throughout your treatment. Just because you are tolerant and need more medication does not mean that you are addicted.

*Physical dependence* means that you may experience symptoms of *withdrawal* if you stop taking regular doses of your opioid too quickly. Common symptoms of withdrawal include restlessness, insomnia, sweating, or nausea/vomiting. These symptoms can be avoided by slowly decreasing the opioid dose. You should not change your dose on your own; speak with your healthcare provider if you feel that you need to have your medication adjusted. Just because you develop withdrawal symptoms if you miss a dose does not mean that you are addicted.

*Addiction* is excessive use of a medication or drug even though it may be harmful to the user. People who take opioids as prescribed usually do not become addicted. It is important to keep up an ongoing dialogue with your healthcare provider and let him know if you feel that you are using your medications for reasons other than pain control or if you feel unable to control how often and how much of your medication you are taking.

#### **What can you expect in terms of pain relief and improvements in your quality of life?**

After starting opioid therapy, you may see the following positive improvements:

- ▶ Your pain level may decrease
- ▶ Your level of function should improve: you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse
- ▶ Your sleep may improve

#### **What if opioid treatment doesn't work?**

If opioid treatment is not appropriate for you, or if you are experiencing side effects, talk with your healthcare provider. She can help to decide on the next best course of action, which may include switching to a different opioid or to a new pain medication. Do not stop taking your opioid medication on your own; make sure to discuss stopping medication with your healthcare provider first.

Opioids are just one part of your pain treatment. Your healthcare provider will partner with you to help reduce your pain, and may also recommend other medications, lifestyle changes, or non-drug treatments that can be used with opioid treatment to obtain the best results.

**FOR MORE INFORMATION:  
Talk to Your Healthcare Professional**



#### **TIPS for Using Opioids to Treat Pain**

- ▶ Take your medication exactly as it is prescribed.
- ▶ Discuss any concerns that you have regarding opioid therapy with your healthcare provider.
- ▶ Let your healthcare provider know if you are experiencing any side effects. She can modify your dose or change your medication.
- ▶ Tell your healthcare provider about any other medication(s) that you may be taking.
- ▶ Keep all of your appointments with your healthcare provider.
- ▶ Keep track of the time when you took your pain medication and the activity that you were doing when your pain occurred.

**REFERENCES** American Cancer Society. Pain control: a guide for people with cancer and their families. Available at: [http://www.cancer.org/docroot/MIT/content/MIT\\_7\\_2x\\_Pain\\_Control\\_A\\_Guide\\_for\\_People\\_with\\_Cancer\\_and\\_Their\\_Families.asp](http://www.cancer.org/docroot/MIT/content/MIT_7_2x_Pain_Control_A_Guide_for_People_with_Cancer_and_Their_Families.asp). • Katz WA. Opioids for nonmalignant pain. *Rheum Dis Clin N Am*. 2008;34(2):387-413. • National Pain Foundation. Addiction and chronic pain. Available at: [http://nationalpainfoundation.org/MyTreatment/MyTreatment\\_Addiction\\_and\\_Chronic\\_Pain.asp](http://nationalpainfoundation.org/MyTreatment/MyTreatment_Addiction_and_Chronic_Pain.asp). All websites accessed January 15, 2009.